K023034
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510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: BIONET Co., LTD

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Guro-Dong, Guro-Gu
Seoul, South Korea

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5-Contact Person: Dong-Joo Kang, CEO

6-Date summary prepared: September 6th, 2002

7- Official Correspondent: Mansour Consulting LLC

8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA

9- Phone: (678) 908-8180

10- Fax: (425) 795-9341

11- Contact person: Jay Mansour, president

12-Device Trade or Proprietary Name: CARDIOTOUCH-3000

13-Device Common or usual name: ECG

14-Device Classification Name: System, ECG Analysis

15-Substantial Equivalency is claimed against the following device:

Bionet's EKG-2000 Cardio Care, 510k #k011328 (refer to Appendix 2 for FDA website printout)

This notification for CARDIOTOUCH-3000 is of the SPECIAL type

16-Description of the Device: (as per User Manual pages17 and 18)

As an electrocardiograph with 12-channel, CARDIOTOUCH-3000 does not only provide parameters and diagnose a patient automatically for patient's electrocardiogram, but also it improves chart management by printing information on an operator as well as on the patient. Furthermore, for the convenience of operators, it is designed so that an operator needs to press a button once to let the machine measure and record patient's electrocardiogram, apply a filter, extract parameters, diagnose a patient automatically then print out a result on an A-4- size report. In addition, the built-in battery helps an operator carry and use CARDIOTOUCH-3000 easily and conveniently for a hospital on wheel and an emergency.

Product features:

- It prints out 12-channel ECG waveforms on an A-4 size report in various channel forms including 3ch+1rhy, 6ch+1rhy, and 12ch rhy.
- It records 1ch rhy for 60 seconds and prints it on an A4-size report
- It displays 12ch rhy simultaneously and continuously in real-time.
- It automatically calculates heart rate, PR interval, QRS interval, QT interval, QTc, and P-R-T axis for diagnosis and displays all of them with electrocardiogram on the report.
- Twenty-five diagnoses are available through auto diagnosis
- It helps a diagnosis with the changing once-recorded electrocardiogram in a filter setup, signal size, printing speed, channel form and rhythm form and then printing them.
- With a built-in battery, it is easy to carry.
- Managing a chart is easy and improved because it prints information on a patient and operator at the same time.

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Basic configuration and accessories:

1- CARDIOTOUCH-3000 body
2- Patient cable (1 EA)
3- User Manual (1 VOL.)
4- ECG Paper (2 EA)
5- Power cable (1 EA)

Options:

1- Battery (built-in type)
2- Protective Ground wire (1 EA)
3- Electrode (10 EA)
4- ECG cream (1 EA)
5- Hanger (1 EA)
6- Cart (1 EA)

17-Intended use of the device: *(Indications for use typed on a separate FDA form)*
The CARDIOTOUCH-3000 is intended to be used under the direct supervision of a licensed healthcare practitioner. The CARDIOTOUCH-3000 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes. The device is intended to acquire, analyze, display, and record electrocardiographic information from adult population. The device is not intended for home use. The device is not designated for intracardial use.

18-Safety and effectiveness of the device:
This device is safe and effective as the predicate device, being a deviation from the previously cleared Bionet's product EKG-2000 Cardio Care.
This is better expressed in the tabulated comparison (Paragraph 19 below)

19-Summary comparing technological characteristics with other predicate device:
Please find below a tabulated comparison supporting that **CARDIOTOUCH-3000** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency detailed chart path is attached.

FDA file reference number	510k #k011328
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	*Comparison result*
Indications for use	Identical: Both CardioCare-2000 and CardioTouch-3000 are detecting and measuring as below parameters to provide and help doctors for making figure out the patient's vital condition. • Accurate Heart Rate • Electrocardiograph wave • Printing the current ECG wave and related numeric values
Target population	Identical: Predicate device and this device are used by cardiologist and sports expert etc. for watching heart patient condition.

Design	Similar: CardioCare-2000 have 2line 16character LCD and CardioTouch-3000 have 320 X 200 dot with back lit LCD.
Materials	Identical: CardioCare-2000 and CardioTouch-3000 are made of ABS materials.
Performance	Identical: ECG leads : Standard 12 leads Sensitivity : 5,10,20, Auto Input circuit : floting input, isolated and defibrillation protected. Input impedence : ≥ 10MΩ Input circuit current : ≤ ±5nV Calibration Voltage : 1mV±2% Time Constant : 100dB or better Frequency response : 0.05~150Hz within -3dB
Sterility	Not applicable
Biocompatibility	Identical: Both of them are satisfied Biocompatibility through using disposable electrode.
Mechanical safety	Identical: A coarse surface and a sharp corners of a device which has cause of patient damage of device are removed and covered.
Chemical safety	Not applicable
Anatomical sites	Not applicable
Human factors	Not applicable
Energy used and/or delivered	Identical: Both of them use the rechargeable battery (100V~240Vac 50/60 Hz and Built-in).
Compatibility with environment and other devices	CardioCare-2000 and CardioTouch-3000 are suitable for EMI and EMC test.
Where used	Identical: Private Check, ER, Hospitals.
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2002

Bionet Company Ltd.
c/o Mr. Jay Mansour
President
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: K023034
Trade Name: CARDIOTOUCH-3000
Regulation Number: Unclassified
Regulation Name: ECG Analysis System
Product Code: LOS
Dated: October 8, 2002
Received: October 21, 2002

Dear Mr. Mansour:

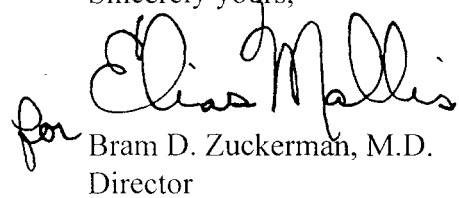
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023034

Device Name: CARDIOTOUCH-3000

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023034

Prescription Use X
(Per 21 C

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